

AMENDMENT

In the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the application. Currently amended claims are shown with additions underlined and deletions in ~~striketrough text~~. No new matter is added by this amendment.

1.-27. (Canceled)

28. (New) A method of quality assurance for a biological diagnostic using mass spectral data from biochips, comprising:

selecting a diverse group of sera, the diverse group of sera having different characteristics;

obtaining information associated with a mass spectrum of each of the sera from the diverse group of sera using each of a plurality of control biochips;

generating a control model based at least in part on the spectra obtained from the diverse group of sera, the control model including at least one control centroid located in an n-dimensional space defined by n mass spectral features included in the control model;

performing mass spectrometry on a test serum applied to a test biochip to obtain a test spectrum associated with the test serum;

mapping the test spectrum obtained from said performing to the n-dimensional space;

if the test spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, submitting the test spectrum to the biological diagnostic.

29. (New) The method of claim 28, further comprising:

classifying a biological state from the test spectrum based on a predetermined biological state model.

30. (New) The method of claim 28, wherein if the test spectrum does not map to the n-dimensional space within an acceptable distance from the control centroid, and the test biochip is a first biochip, the method further comprising:

repeating the steps of performing and mapping for a second biochip different from said test biochip.

31. (New) The method of claim 28, said selecting further comprising:

selecting at least two different sera from a pool of diverse sera, the pool of diverse sera consisting of: sera from healthy males, sera from healthy females, sera from males afflicted with a disease, sera from females afflicted with a disease, sera from persons of different races, and sera from people of different ages.

32. (New) The method of claim 28, wherein said generating includes:

identifying at least one cluster in common to the sera of the diverse group of sera and the plurality of different control biochips; and

selecting only one cluster as the control centroid of the control model.

33. (New) The method of claim 28, wherein the obtaining information includes:

obtaining information on sera applied to at least two types of biochips, the types of biochips being at least two of a cationic exchange biochip, an anionic exchange biochip, and an immobilized metal biochip.

34. (New) The method of claim 28, wherein the test biochip is one of the plurality of different biochips.

35. (New) The method of claim 28, wherein the test biochip is not one of the plurality of different biochips.

36. (New) A method of quality assurance for a biological diagnostic employing a control model generated based on mass spectra obtained from application of a plurality of different sera

to a plurality of different biochips, the control model including at least one control centroid located in an n-dimensional space defined by n mass spectral features included in the model, comprising:

applying a test serum to a spot on a test biochip;

performing mass spectrometry on the test serum to obtain test spectral data associated with the test serum and the test biochip; and

mapping the test spectrum to the n-dimensional space; and

if the test spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, submitting the test spectrum to the biological diagnostic.

37. (New) The method of claim 36, where the submitting includes submitting the test spectrum to the biological diagnostic to determine if the test serum exhibits a particular biological state.

38. (New) The method of claim 36, wherein said performing mass spectrometry includes performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

39. (New) The method of claim 36, wherein said biological diagnostic is a disease model capable of determining if the test serum exhibits a disease state associated with the disease model.

40. (New) A method of quality assurance for a biological diagnostic using mass spectral data from the application sera to a biochip, comprising:

providing in an n-dimensional space defined by n mass spectral features a location of at least one control centroid associated with one biochip and that distinguishes the one biochip from at least one second biochip;

generating a test mass spectrum from the application of a test serum to a test biochip;

mapping the test mass spectrum to the n-dimensional space; and

if the test mass spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, certifying the test mass spectrum for analysis with the biological diagnostic.

41. (New) A quality control method for a bioassay that generates mass spectral data from the application of a serum to a biochip, comprising:

providing a location in an n-dimensional space defined by n mass spectral features of at least one control centroid associated with a preferred biochip;

providing a location in the n-dimensional space of at least one test centroid associated with a test sample;

comparing the at least one test centroid to the at least one control centroid to determine the displacement in the n-dimensional space of the at least one test centroid from the at least one control centroid; and

determining a degree of error between the test centroid and the control centroid.

42. (New) The quality control method of claim 41, wherein the test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one control centroid is within an acceptable distance.

43. (New) The quality control method of claim 41, wherein the sample is serum.

44. (New) The quality control method of claim 41, wherein the mass spectral data is generated by surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

45. (New) A quality control method for a bioassay that generates mass spectral data from a sample that is applied to a biochip, comprising:

providing a location in an n-dimensional space defined by n mass spectral features of at least one control centroid associated with a preferred biochip;

providing a location in the n-dimensional space of at least one test centroid associated with a test sample; and

comparing the at least one test centroid to the at least one control centroid to determine the displacement in the n-dimensional space of the at least one test centroid from the at least one control centroid; wherein the magnitude of the displacement is an indicator as to reliability of the bioassay applied to the test sample.

46. (New) The quality control method of claim 45, wherein the test sample is accepted for analysis if the displacement of the at least one test centroid from the at least one control centroid is within an acceptable distance.

47. (New) The quality control method of claim 45, wherein the sample is serum.

48. (New) The quality control method of claim 45, wherein the mass spectral data is generated by surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

49. (New) A method of quality assurance for a bioassay that generates mass spectral data from the application of a serum to a biochip, comprising:

selecting a diverse group of sera, the diverse group of sera having different characteristics;

selecting a control biochip of a predetermined type;

obtaining information associated with a mass spectrum of each of the sera from the diverse group of sera using the control biochip;

generating a control model based at least in part on the spectra obtained from the diverse group of sera, the control model including at least one control centroid located in an n-dimensional space defined by n mass spectral features included in the control model;

performing mass spectrometry on a test serum applied to a test biochip to obtain a test spectrum associated with the test serum;

mapping the test spectrum obtained from said performing to the n-dimensional space;

if the test spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, certifying that the test biochip is acceptable for the bioassay.

50. (New) The method of claim 49, wherein the control biochip is one of a cationic exchange biochip, an anionic exchange biochip, and an immobilized metal biochip.

51. (New) A method of quality assurance for a biological diagnostic employing a control model generated based on mass spectra obtained from application of a plurality of different sera to a preferred biochip, the control model including at least one control centroid located in an n-dimensional space defined by n mass spectral features included in the model, comprising:

applying a test serum to a spot on a test biochip;

performing mass spectrometry on the test serum to obtain test spectral data associated with the test serum and the test biochip; and

mapping the test spectrum to the n-dimensional space; and

if the test spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, certifying that the test biochip is acceptable for the biological diagnostic.

52. (New) The method of claim 51, where the submitting includes submitting the test spectrum to the biological diagnostic to determine if the test serum exhibits a particular biological state.

53. (New) The method of claim 51, wherein said performing mass spectrometry includes performing surface enhanced laser desorption/ionization time of flight (SELDI-TOF) mass spectrometry.

54. (New) The method of claim 51, wherein said biological diagnostic is a disease model capable of determining if the test serum exhibits a disease state associated with the disease model.